

# Financial Impact of Recently Enacted Health Insurance Mandates

Arizona Health Care Cost  
Containment System

October 2001

# Financial Impact of Recently Enacted Health Insurance Mandates

Arizona Health Care Cost  
Containment System

October 2001

---

William M. Mercer, Incorporated  
3131 E. Camelback Road  
Suite 300  
Phoenix, AZ. 85016

602 522 6500

---

# Contents

Introduction .....	1
Administration .....	4
Description .....	4
Continuity of Care .....	4
Standing Referrals .....	4
Assumptions .....	5
Financial Impact and Conclusions .....	5
Access to Medical Supplies .....	6
Description .....	6
Readily accessible vendors .....	6
Assumptions .....	6
Financial Impact and Conclusions .....	6
Pharmacy .....	8
Description .....	8
Off-label use .....	8
Prescription formularies .....	8
Medical foods .....	8
Assumptions .....	9
Financial Impact and Conclusions .....	9
Direct Access to Care .....	10
Description .....	10
Chiropractic .....	10
Access to specialists (including chiropractic) .....	10
Assumptions .....	10
Financial Impact and Conclusions .....	10
Emergency Services .....	12
Description .....	12
Prior authorization and ambulatory .....	12
Assumptions .....	12
Financial Impact and Conclusions .....	12
Clinical Trials .....	14
Description .....	14
Cancer clinical trials .....	14
Assumptions .....	15
Financial Impact and Conclusions .....	15
Appendix A .....	17
Kaiser Study .....	17
Memorial Sloan-Kettering Cancer Center Study from May 20, 2000 .....	17

---

# Introduction

William M. Mercer, Incorporated (Mercer) has produced this briefing paper for the Arizona Health Care Cost Containment System (AHCCCS) as part of the Arizona State Planning Grant, which is funded by the Health Resources and Services Administration (HRSA). Mercer conducted an independent cost study to estimate the financial impact of health insurance mandates recently enacted by House Bill 2600 (H.B. 2600).

Mercer is the world's leading employee benefits, compensation, and human resources consulting firm, offering the most comprehensive human resources consulting services in the industry. Mercer's Health Care and Group Benefits consultants are experts in employee benefits programs and primarily provide consulting services to employer and government purchasers of health care plans.

In preparing this report, Mercer's expert panel of actuaries and consultants reviewed available literature, including estimates prepared by the Congressional Budget Office in 1998 (CBO '98) and 2001 (CBO '01). Also, Mercer relied on information that we prepared for a similar report on proposed Arizona mandates in February 1999. These cost impact estimates were based on sound actuarial assumptions and methods. The report describes the specific provisions being analyzed, the assumptions used to help develop estimates of the costs of the provisions, and Mercer's resulting cost estimates.

The specific mandates that Mercer analyzed, within H.B. 2600, provide for the expansion of patients' health care rights. The initiatives passed by this bill are intended to expand the range of choices available to health plan members. However, these choices will result in cost implications for the health plans, employer groups, providers of care, and enrollee population that they are intended to help.

The cost of implementing these provisions depends upon several factors. These factors include, but are not limited to, current business practices, the cost savings associated with managed care plans, and the influence of managed care treatment patterns on all health care delivery. Additionally, some of these mandates may be open to interpretation due to the broader language used, when compared to similar federal provisions. In the course of Mercer's analysis, it was found that even those mandates that appeared relatively clear could be interpreted to have different meanings by different people.

Furthermore, Mercer developed the cost estimates for these mandates based upon conventional assumptions. For example, under the mandate that deals with prescription drugs, Mercer assumes that current drug exclusions, such as experimental drugs, will remain intact in the future. Mercer's analysis also assumes that coverage of clinical trials will remain narrowly defined to include only cancer-treated patients. Should a broader definition be applied in the future to various mandates, the cost impact could be much greater than stated in this report.

Additionally, while Mercer has calculated the cost impact of these mandates, the actual implications at a single point in time may differ due to a specific health plan's organizational structure. Another method of calculating the cost impact of these mandates would be to use actual claims experience data from health insuring organizations. Such information is not currently available due to the short time period for which these mandates have been in effect.

The following table summarizes the mandates that were analyzed by Mercer. Included are the Department of Insurance section numbers for Group Health Insurance (Group), Individual Health Insurance (Individual), Health Care Service Organizations (HCSO), and Hospital, Medical, Dental, and Optometric Service Corporation (HMDOSC).

#### Health Insurance Benefits Mandated By Arizona Law

Mandate	Group	Individual	HCSO	HMDOSC
<b>Administration</b>				
<i>Continuity of care</i>	N/A	N/A	20-1057.04	20-841.06
<i>Standing referrals</i>	N/A	N/A	20-1057.01	20-841.04
<b>Access to Medical Supplies</b>				
<i>Readily accessible vendors</i>	N/A	N/A	20-1057.05	20-841.07
<b>Pharmacy</b>				
<i>Off-label use for cancer treatment</i>	20-1402 20-2326	20-1342	20-1057	20-826
<i>Prescription formularies:</i>				
<i>a) Process for receiving non-formulary drugs and process for receiving formulary and non-formulary drugs during non-business hours</i>	N/A	N/A	20-1057.02	20-841.05
<i>b) Must allow benefits for at least 60 days after a health plan's removal of a drug from the formulary</i>	N/A	N/A	20-1057	20-841.05
<i>Coverage of medical foods to treat inherited metabolic disorders</i>	20-1402 20-2326	20-1342	20-1057	20-826
<b>Direct Access to Care</b>				
<i>Chiropractic</i>	20-1406	20-1376	20-1057	20-841
<i>Access to specialty care</i>	N/A	N/A	N/A	N/A
<b>Emergency Services</b>				
<i>Ambulatory and prior authorization</i>	20-2803	20-2803	20-2803	20-2803
<b>Clinical Trials</b>				
<i>Covered patient costs; cancer</i>	20-1402	20-1342	20-1057 20-2326	20-826

H.B. 2600 made additional reforms to statutes governing health care insurers and coverage, relating to anti-retaliation of health care providers, third party intermediaries, financial incentives, health care appeals, and claims payments and liability. These changes will affect the practices of HMOs, resulting in an increase in the cost of coverage. However, these reforms are not benefit coverage mandates, and therefore, are beyond the scope of this analysis.

The second table is a summary of each of the analyzed mandate's cost estimate. Mercer compares its own cost estimate with that of two CBO estimates. The impact shown is for insured products only, which represents approximately 60 percent of the active employee population in Arizona.

#### Estimated Cost Impact Of Recently Enacted Mandates

Provision	Mercer Estimated Impact	CBO '98 Estimated Impact	CBO '01 Estimated Impact
<b>Administration</b>			
<i>Continuity of care</i>	0.3%	0.2%	0.2%
<i>Standing referrals</i>	0.1%	N/A	0.1%
<b>Access to Medical Supplies</b>			
<i>Readily accessible vendors</i>	0.2%	N/A	N/A
<b>Pharmacy</b>			
<i>Off-label use for cancer treatment</i>	1.1%	N/A	N/A
<i>Prescription formularies:</i>	N/A	N/A	N/A
<i>a) Process for receiving non-formulary drugs and process for receiving formulary and non- formulary drugs during non-business hours</i>	N/A	N/A	N/A
<i>b) Must allow benefits for at least 60 days after a health plan's removal of a drug from the formulary</i>	N/A	N/A	N/A
<i>Coverage of medical foods for inherited metabolic disorders</i>	N/A	N/A	N/A
<b>Direct Access to Care</b>			
<i>Chiropractic</i>	3.0%	N/A	N/A
<i>Access to specialty care</i>	0.4%	0.1%	0.1%
<b>Emergency Services</b>			
<i>Ambulatory and prior authorization</i>	0.4%	N/A	0.4%
<b>Clinical Trials</b>			
<i>Covered patient costs; cancer</i>	0.2%	0.1%	0.1%

SOURCES: William M. Mercer, Incorporated and Congressional Budget Office

---

# Administration

For the purpose of our analysis, the mandates pertaining to continuity of care and standing referrals have been combined due to the primary impact from these provisions being on the administrative cost to the health plans.

---

## Description

### Continuity of Care

This mandate requires that health plans allow enrollees to continue an ongoing course of treatment with a network health care provider for up to 30 days after the provider leaves the plan's network.

Additionally, this provision states that a health care plan shall allow a new enrollee to continue treatment for a life threatening condition with a non-participating health care provider for up to 30 days after enrollment. It also allows a new enrollee who has entered the third trimester of pregnancy to receive services from her current non-participating health care provider for the delivery and care up to six weeks following the delivery.

The mandate also requires non-participating providers to accept reimbursement as payment in full from the health plan at established rates, comply with quality assurance and information requirements related to care, and comply with the health plan's policies for referral and pre-authorization.

Health care service organizations must also include, in its disclosure form, a description of the insurer's continuity of care policies.

### Standing Referrals

This mandate requires that health care insurers must establish a procedure that allows enrollees who have a degenerative, life threatening, chronic, or disabling condition to receive a referral to a health care specialist.

The standing referral shall be pursuant to a treatment plan that is approved by the health care plan in consultation with the primary care physician, specialist, and enrollee. The health care plan may also limit the number of visits, as well as the time period for which an enrollee may receive a standing referral.

Finally, this mandate specifies that a standing referral shall continue if the primary care physician leaves the network.

---

## Assumptions

- The continuity of care and standing referral sections impose a significant administrative burden on the health plans due to notification requirements. Administrative costs are estimated at 15 percent of total plan costs.
- Provider termination notices would be issued to all enrollees to ensure notification to all enrollees in possible course of treatment.
- Due to continuous changes in provider networks, most plans will send notices on a monthly basis.

---

## Financial Impact and Conclusions

Mercer estimates the overall impact of the continuity of care section to be an increase in health care premiums of 0.3 percent. The CBO '01 estimate for a similar provision was found to be 0.2 percent. This estimate from the CBO remains unchanged from the CBO '98 estimate. The difference in the estimates is due to the expanded time frames proposed under this mandate as compared to the federal proposal.

Additionally, there are more individuals enrolled in managed care plans in Arizona than the national average. Due to the larger number of enrollees, Arizona health plans will feel a greater administrative impact.

Mercer's estimate, on the financial impact of standing referrals on health plans, is that premiums would increase 0.1 percent for the administrative work of contracting with other specialists outside the network in the case that an appropriate specialist within the network is unavailable. The CBO '01 estimates showed that timely access to specialists would have an impact of 0.1 percent on health care premiums.

There is no data provided by the CBO that reflects the issue of a standing referral. Therefore, because of the similarity between "timely" access to specialists, which is discussed in the CBO '01, and a standing referral, Mercer has decided the information provided by the CBO '01 on this matter to be relevant.

Provision	Mercer Estimated Impact	CBO '98 Estimated Impact	CBO '01 Estimated Impact
<b>Administration</b>			
<i>Continuity of care</i>	0.3%	0.2%	0.2%
<i>Standing referrals</i>	0.1%	N/A	0.1%



---

# Access to Medical Supplies

---

## Description

### Readily accessible vendors

This mandate requires that health care insurers that provide coverage for medical equipment, appliances, devices, and supplies must also provide that coverage through participating vendors who are reasonably accessible, by location and hours of service, to enrollees.

---

## Assumptions

- Mercer used the CBO '98 and American Association of Health Plans (AAHP) estimates that rural areas will experience cost increases of 6 percent for required optional coverage due to elimination of price discounts under this provision.
- This provision provides open access to any medical supply provider, whether they are in or out of the network.
- Mercer analysis assumes that durable medical equipment (DME) accounts for 1 percent of all health care costs, with an average discount of 20 percent based upon the 1998 Mercer/Foster Higgins Survey of Health Plan Costs.
- Lack of clarity exists as to what constitutes a “readily accessible” vendor, and therefore will increase plan liability.
- According to the Bureau of Labor Statistics (BLS), 13 percent of employees live in rural Arizona; 60 percent of which are enrolled in an HMO/POS/PPO option.

---

## Financial Impact and Conclusions

Mercer anticipates readily accessible vendors to have a cost impact of 0.2 percent since volume guarantees for discount purposes would effectively be impossible under this provision.

Rural areas have a likelihood of limited supplies due to the lack of vendors. Additionally, dependent upon how the state, as well as the HMOs, defines readily accessible, may mandate a higher contract rate in rural areas.

There are no CBO '01 estimates of a similar provision, nor was there an estimate from the CBO '98.

Provision	Mercer Estimated Impact	CBO '98 Estimated Impact	CBO '01 Estimated Impact
<b>Access to Medical Supplies</b> <i>Readily accessible vendors</i>	0.2%	N/A	N/A

---

# Pharmacy

This mandate, under revisions made by H.B. 2600, requires that health plans covering prescription drugs must (1) cover off-label use drugs for cancer treatment, (2) have a process for receiving medically necessary non-formulary drugs (including during non-business hours), and allow benefits for at least 60 days after notice of the health plan's removal of a drug from the formulary, and (3) cover medical foods used to treat inherited metabolic disorders, such as Phenylketonuria (PKU).

---

## Description

### Off-label use

This provision of the pharmaceutical mandate prohibits all health care plans that provide coverage for prescription drugs from excluding coverage for any drug prescribed for the treatment of cancer, on the basis the drug has not been approved for treatment of the specific type of cancer, as long as the drug has been recognized by at least one acceptable medical reference as a safe and effective treatment. This provision also stipulates that health care insurers are not required to provide coverage for a drug determined to be experimental, has not been approved by the FDA, or is not on the health plan's formulary.

### Prescription formularies

As summarized above, all health care plans shall have a procedure for enrollees to obtain non-formulary drugs if either the treating provider deems the drug necessary, the formulary's equivalent has been ineffective in treatment, or the formulary's drug causes adverse reactions.

Additionally, health care plans should provide notice of formulary changes to each contracted pharmacy plan, and are prohibited from limiting or excluding coverage for a prescription drug that was a previously approved drug, but has been removed from the formulary, for at least 60 days.

Three tier pharmacy benefits are exempt from the above provisions.

### Medical foods

This provision of the mandate requires that health plans that cover prescription drugs must also cover medical foods that are used to treat inherited metabolic disorders. However, by further reviewing this provision, it also states that a health plan must only cover a minimum of 50 percent of all formulas and foods (low protein), up to \$5,000, needed to treat enrollees with such a disorder.

Unlike the other provisions of the pharmaceutical mandate, coverage of medical foods for inherited metabolic disorders, such as PKU, is not covered by H.B. 2600. Instead, this mandate was adopted as part of House Bill 2043 on April 18, 2000.

## Assumptions

- Mercer assumes that prescription drug costs to be 16 percent of premiums for HMOs and 15 percent for PPOs.
- Mercer's analysis excludes experimental drugs.
- Cost estimates assume that the exclusions or requirements for rigorous prior authorization for treatment of hair loss due to male pattern baldness, smoking cessation, use of human growth hormone, infertility, and use of Viagra would remain effective.

## Financial Impact and Conclusions

Mercer's cost impact projection, for the overall pharmaceutical mandate, is an increase in premiums of 1.2 percent for HMO health plans and 0.9 percent for POS/PPO plans. This will further result in a total cost impact of 1.1 percent. The Arizona mandate would permit each contracting physician to determine medical necessity for prescription drugs on a case-by-case basis.

No CBO '98 estimates were made of a similar federal provision. The federal bill provision (Section 107) requires health plans using restrictive plan formularies to have written policies, as well as a process for making exceptions.

The CBO '01 changed its position on the estimated impact that prescription drugs will have on overall health plan costs. However, this impact is miniscule, at less than .05 percent. Mercer believes that this CBO '01 estimate is due to increased administrative costs rather than the prescription drugs themselves.

Provision	Mercer Estimated Impact	CBO '98 Estimated Impact	CBO '01 Estimated Impact
<b>Pharmacy</b>	1.1%	N/A	N/A
<i>Off-label use for cancer treatment</i>	N/A	N/A	N/A
<i>Prescription formularies</i>			
<i>a) Process for receiving non-formulary drugs and process for receiving formulary and non-formulary drugs during non-business hours</i>	N/A	N/A	N/A
<i>b) Must allow benefits for at least 60 days after a health plan's removal of a drug from the formulary</i>	N/A	N/A	N/A
<i>Coverage of medical foods to treat inherited metabolic disorders</i>	N/A	N/A	N/A

---

# Direct Access to Care

Direct access to care has been an ongoing concern of those parties looking to revamp the health care delivery system. For purposes of Mercer's analysis, only the sections of direct access that deal with chiropractic care and access to specialists will be evaluated, due to the fact that other mandates pertaining to direct access to care are federally required.

---

## Description

### Chiropractic

All health care plans shall provide benefits covering care by network chiropractic providers for a minimum of twelve self-referred chiropractic visits during any one contract period. As in the past, health care plans shall maintain an adequate number of chiropractic providers to assure reasonable accessibility to enrollees.

Additionally, chiropractic care is referred to as only the treatment of non-surgical/non-invasive neck and back pain through physiotherapy musculoskeletal manipulation, as well as other physical corrections of musculoskeletal conditions within the scope of a chiropractor's practice.

### Access to specialists (including chiropractic)

This section provides in the event that an enrollee's primary care physician leaves the network plan after providing the enrollee with a referral to a network specialist, the health care plan shall allow the enrollee to receive care from the network specialist without having to obtain another referral from a PCP within the plan.

---

## Assumptions

- Specialist referrals may be made by any provider of care, including specialists referring to other specialists.
- Mercer used the CBO '98 estimates that rural areas will experience cost increases of 6 percent for required optional coverage due to elimination of price discounts under this provision.
- According to the Bureau of Labor Statistics (BLS), 13 percent of employees live in rural Arizona; 60 percent of which are enrolled in an HMO/POS/PPO option.

---

## Financial Impact and Conclusions

For the purposes of this report, Mercer is concentrating only on the sections of direct access to care involving chiropractic care and access to specialists. Access to specialists is a provision included in H.B. 2600, but is not one of the specifically listed mandates that Mercer was asked to

provide analysis. However, Mercer found that the cost impact of access to specialists directly effects chiropractic care, and the cost implications associated with such care. Therefore, the cost estimate is broken down as follows:

1. *Access to chiropractic care from a participating provider.*

Mercer expects this provision of the mandate to increase premiums by 3.0 percent. The CBO '01 has not provided an estimate for this provision because there is no corresponding proposed federal legislation.

2. *Necessary or specialty care from any qualified health care provider in accordance with applicable referral procedures. Requires health plans to contract with "sufficient" number of physicians and chiropractors to meet member needs.*

It is estimated that this provision would have an overall impact of a 0.4 percent increase on health plan premiums. The CBO '98 previously estimated an impact of only 0.1 percent. As of the CBO '01, this mandate was still estimated to have an overall increase in premiums of 0.1 percent. The estimates differ due to the broader language of the state mandate. This provision has been estimated to significantly impact health plans in rural areas due to the lack of risk sharing cost controls.

Provision	Mercer Estimated Impact	CBO '98 Estimated Impact	CBO '01 Estimated Impact
<b>Direct Access to Care</b>			
<i>Chiropractic care</i>	3.0%	N/A	N/A
<i>Access to specialty care</i>	0.4%	0.1%	0.1%

---

# Emergency Services

For the purposes of this analysis, the sections pertaining to prior authorization and ambulance services have been combined, as they have been in the state of Arizona health insurance mandates.

---

## Description

### Prior authorization and ambulatory

This mandate requires that health care plans engaging in utilization review to determine whether any emergency services rendered by a provider or hospital were medically necessary to consider whether a prudent layperson would have sought the emergency services in question if the layperson were faced with similar medical symptoms as the enrollee receiving the services.

The Balanced Budget Act (BBA) of 1997 requires that emergency services must be covered by a health insurer without prior authorization, regardless of whether the enrollee obtains the services in or out of the network.

The BBA addresses emergency services using a prudent layperson standard, defined as “a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possess an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in placing the health of the individual (or, with respect to a pregnant women or her unborn child) in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.”

---

## Assumptions

- Enrollees that previously received authorization from their health plans before going to the emergency room will no longer contact that health plan beforehand.

---

## Financial Impact and Conclusions

This mandate would not be substantially different than the federal provision, and is therefore viewed by Mercer that the cost impact related to emergency services would be relatively similar to estimates established by the CBO. That being said, the CBO '01 cost estimate anticipates a 0.4 percent increase in premium related to access for emergency care.

The elimination of prior authorization for emergency services will only slightly decrease the prior authorization administrative burden for health plans, as few patients typically contacted

their health plan on the way to the emergency room regardless of the requirement. However, this easing of the administrative requirement may actually increase the medical costs to a health plan, as those few members that previously would have called the health plan for authorization and been diverted to a more appropriate and less costly setting, may now end up in the ER for non-emergency conditions.

Previously, the health plan used nurses to evaluate the patients' condition over the phone, and the members were instead referred to a less intensive and costly center for care. This referral to a less intense care center still occurs, but not as often with the lack of prior authorization for emergency care visits. Therefore, the number of inappropriate ER visits may increase, and possibly the number of inappropriate hospital admissions.

While concurrent and retrospective review will still evaluate hospital admissions for medical necessity, ER visits are not typically reviewed for medical necessity. Therefore, the utilization related to ER visits will increase, resulting in higher health plan costs.

Provision	Mercer Estimated Impact	CBO '98 Estimated Impact	CBO '01 Estimated Impact
<b>Emergency Services</b> <i>Prior authorization &amp; Ambulatory</i>	0.4%	N/A	0.4%



---

# Clinical Trials

Two case studies, with opposing viewpoints as to the cost effects of cancer clinical trials, are listed in Appendix A.

---

## Description

### Cancer clinical trials

This mandate requires that insurers must pay all “covered patient costs” for enrollees who participate in cancer clinical trials at an Arizona institution. Furthermore, it is indicated that this mandate would require health plans to provide coverage for all routine enrollee costs incurred through a clinical trial if the costs would also be covered for non-investigational treatment under certain conditions.

Based on a National Cancer Institute Web site, there are 231 clinical trials related to cancer treatment associated with Arizona. However, many of these trials have very few patients, and the studies are linked to many other states. In addition, there may be many clinical cancer trials based outside of Arizona that have Arizona residents as part of the study.

The number of patients in the clinical trials from Arizona may vary tremendously over time, based on the number of patients with the type of cancer under study, research methodology, and willingness of patients with that type of cancer to participate in the study. The Arizona Clinical Research Center in Tucson, for example, has the following number of patients in various types of cancer trials as of February 2001:

Type of cancer study	Number of people in trial
Tumor necrosis	1
Prostate cancer	5
Breast cancer	29
Chemotherapy	21
Chemo nausea	27
Gastrointestinal cancer	12
Genitourinary	2
Gynecology	2
General	1
Leukemia	19

Type of cancer study	Number of people in trial
Lymphoma	4
Melanoma	4
Pancreatic	7
<b>Total</b>	<b>134</b>

[Http://www.amrllc.com/Research/Indications/Oncology.htm#Breast Cancer](http://www.amrllc.com/Research/Indications/Oncology.htm#Breast Cancer)

It is unclear if all the people in these trials are from Arizona. With additional research, a better estimate of the number of patients in cancer trials may be determined, as well as the associated costs that a health plan may also be held accountable.

---

## Assumptions

- The Arizona provision will have greater impact if the federal legislation does not pass. Arizona would then become a more frequent location for clinical trials due to a lower cost of conducting the trial.
- Insurers will react conservatively since there are large unknown costs associated with this provision.
- The CBO '01 states that there will be a greater long-term impact since the number and expense of clinical trials will increase three-fold.
- There is no restriction imposed as to the phase or type of trial.
- The coverage includes all drug trials and devices.
- No geographical service area limits are imposed as to where the trial is conducted.
- An illness for which there are no effective standard treatments is interpreted to mean an incurable disease.

---

## Financial Impact and Conclusions

Mercer anticipates a cost increase of 0.2 percent due to “covered patient costs” for cancer clinical trials. Prior Mercer estimates indicated an overall impact of 0.9 percent resulting from the adoption of a similar provision that included the coverage of all clinical trials. In addition, the CBO '01 and CBO '98 estimate a 0.1 percent increase to health plan premiums as a result of a similar federal provision.

As a result of this mandate, health plans will inherit liability for the enrollee involved in cancer clinical groups for trials. Since no geographical service area limits are imposed, this type of coverage could create a migration of individuals to Arizona to take advantage of this benefit.

Provision	Mercer Estimated Impact	CBO '98 Estimated Impact	CBO '01 Estimated Impact
<b>Clinical Trials</b> <i>Covered patient costs; cancer</i>	0.2%	0.1%	0.1%

---

# Appendix A

---

## Kaiser Study

Concerns about the direct cost of medical care delivered to participants in national cooperative oncology clinical trials compared to the costs of standard medical care may be a stumbling block to increased oncology clinical trial participation. During the years 1994-1996, 203 patients were entered into randomized NSABP (B-23, B-24, B-25, B-26, B-28) and SWOG (9035, 9061, 9313, 9410, others) trials through a large established prepaid closed staff model HMO (Kaiser Permanente, Northern California), where outside plan medical care is quite uncommon.

Eighty-nine percent of patients were in adjuvant trials with breast cancer predominating over colon and melanoma. An age matched, specific clinical trial eligible, contemporary control was found through a computerized search and confirmed by chart review for 135 of these patients. Trial patients and controls were 89 percent female with a mean age of 51.6 years. The direct cost of medical care delivered over a 6 and 12 month period from a defined anchor point was obtained using an automated cost accounting system assigning fully loaded costs (not charges) for all medical care for the trial patients and their matched control. The mean one year cost in dollars of trial patients was 17,003 compared to 15,516 for controls,  $p=0.49$  (paired t-test). If randomized autologous bone marrow transplant versus control studies were removed, the one year cost for trial patients (124 matched pairs) was 15,041 versus 15,185 for the controls. If customary prices had been paid for study supplied chemotherapy drugs, the mean one-year costs for trial patients would have been 19,675 versus 15,516 for controls, ( $p<0.01$ ). The costs of research infrastructure, data management, and research specific physician time have not been included. Even including some BMT studies, participation in selected national cooperative group trials as described did not increase or decrease medical care costs during the first year. ([http://www.asco.org/prof/me/html/99abstracts/hsr/m\\_1610.htm](http://www.asco.org/prof/me/html/99abstracts/hsr/m_1610.htm))

---

## Memorial Sloan-Kettering Cancer Center Study from May 20, 2000

Despite the commonly held opinion by insurers that it is more expensive to treat cancer patients in clinical trials, a new study shows that it does not cost more and may actually cost less. A comparison of patients receiving chemotherapy for solid tumors revealed that the treatment for those patients enrolled in a clinical trial cost 17 percent less than those receiving standard care. Dr. George Bosl, chairman of the Department of Medicine at Memorial Sloan-Kettering Cancer Center and co-author of the paper, reported the results at the 36th annual meeting of the American Society of Clinical Oncologists in New Orleans, Louisiana. "Payers, including Medicare, often believe that the costs for patients in clinical trials are more than standard care," explained James Quirk, Senior Vice President for Research Resources Management at Memorial Sloan-Kettering Cancer Center and the study's first author. "However, when we analyzed the average costs for inpatient care, outpatient care and physician charges, we found clinical trial

costs to be similar or less than those for the standard of care. The total costs per patient were \$30,775 for those in clinical trials compared to \$37,055 receiving standard care."  
([http://www.mskcc.org/patients\\_n\\_public/info\\_for\\_\\_\\_/journalists/press\\_releases/study\\_shows\\_clinical\\_trials\\_for\\_cancer\\_patients\\_cost\\_less\\_than\\_standard\\_care\\_body.html](http://www.mskcc.org/patients_n_public/info_for___/journalists/press_releases/study_shows_clinical_trials_for_cancer_patients_cost_less_than_standard_care_body.html))